IoT Hero NFANT Goes from Idea to FDA Approval in 90 Days
Bluetooth Low Energy | Healthcare Technology | Case Studies

Customer's Needs
- Pre-certified technology stack
- Bluetooth Low Energy
- Affordable Bill of Materials

Results
- Accelerated prototyping
- Rapid FDA Clearance
- NICU data collection to cloud

Products
- BLE113 Bluetooth Low Energy Module

Using BLE113 to Build the First IoT Device Cleared for NICU

Situation:
NFANT Labs®, an emerging medical device company, had a concept for a breakthrough neonatal feeding solution and wanted to bring it to market quickly. Based on clinical trials, they knew their device needed Bluetooth® connectivity, a simple interface, and an affordable price. Being in a highly regulated industry, they also understood the many complexities beyond technical design involved in their road to success. They knew a pre-certified technology stack would reduce risk of technological roadblocks and help accelerate their time to market.

Solution:
After considering a wide spectrum of design options, both in-house and commercial-off-the-shelf, NFANT Labs chose the Silicon Labs BLE113 Bluetooth Smart Module based on its reputation in the market and its pre-certified technology stack. They intentionally chose a module and sensors that were already in large-volume, commercial applications in order to capitalize on reliable, yet affordable parts. In a matter of months, they went from concept to FDA-approval of their nfant® Feeding Solution, becoming the first-ever FDA-cleared IoT medical device for the NICU.

“Going from concept to FDA submission in a matter of months with everything going smoothly: that doesn't happen without a great technology stack. Silicon Labs had us covered.”

Tommy Cunningham | Cofounder and COO of NFANT Labs

Benefit:
The nfant Feeding Solution is one of the fastest medical devices ever deployed to the field. Its simple, small, Bluetooth-enabled design stands out from the expensive, standalone, legacy medical devices typically found in the NICU. With an affordable BoM and rapid adoption in the market, NFANT Labs is poised to increase revenue and expand their IoT medical solutions beyond the NICU. Best of all, the nfant Feeding Solution captures and stores data in the cloud, providing clinicians with objective insights to better-inform their future decision making, helping reduce stress on patients and improve infant lives.

Bluetooth Low Energy Fundamentals:

- **Ultra-low power consumption**: can run more than a year on a coin cell battery
- **Flexible**: connects to most consumer mobile devices like smart phones, tablets, and PCs
- **Supported by major platforms**: iOS, Android® 4.3, Windows® 8, OSX, and Linux®
- **Reliable and Robust**: AFH, retransmissions and 24bit CRCs
- **Secure**: Paring, privacy, MITM protection, and AES-128